

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

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Applicant's or agent's file reference 12221WO:KG/GH		FOR FURTHER ACTION		See Form PCT/PEA/416
International application No. PCT/GB2004/002815		International filing date (day/month/year) 30.06.2004	Priority date (day/month/year) 30.06.2003	
International Patent Classification (IPC) or national classification and IPC C12N1/20, C12P19/14, C07H3/06, A61K31/70, A61P1/04				
Applicant CLASADO INC. et al.				
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> sent to the applicant and to the International Bureau) a total of sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>				
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application</p>				
Date of submission of the demand 25.01.2005		Date of completion of this report 30.06.2005		
Name and mailing address of the International preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized Officer Telephone No. +49 89 2399- 2132 Dardeli, W.		



INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/GB2004/002815

Box No. 1 Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
 - ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

126 as originally filed

Claims, Numbers

1-21 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
 - ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing *(specify)*:
 - ☐ any table(s) related to sequence listing *(specify)*:
 4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
 - ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing *(specify)*:
 - ☐ any table(s) related to sequence listing *(specify)*:

* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	3-5,8,9,11-13,15-17,20,21
	No: Claims	1,2,6,7,10,14,18,19
Inventive step (IS)	Yes: Claims	3-5,15
	No: Claims	8,9,11-13,16-17,20,21
Industrial applicability (IA)	Yes: Claims	1-21
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item V

**Reasoned statement with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

The citations are:

D1/ Carbohydr. Res. 201, 15-123 (1990)

D2/ Biotechnol. Appl. Biochem. 19, 341-354 (1994)

D3/ WO-A-01 90 317

D1 describes the enzymatic preparation of a mixture of galacto-oligosaccharides by culturing a strain of *Bifidobacterium bifidum* having galactosidase activity on lactose. The oligosaccharide mixture so obtained contains disaccharides, trisaccharides, tetrasaccharides and pentasaccharides (see page 121), in particular Gal-Gal, Gal-Gal-Glc, Gal-Gal-Gal-Glc etc.. The subject-matter of claims 1, 2, 6, 7, 10, 14, 18 and 19 lacks novelty over D1.

D2 mentions that galacto-oligosaccharides may be useful in medical therapy of gastrointestinal diseases (see page 341-2). Another practical application of galacto-oligosaccharides obtainable from *Bifidobacterium bifidum* is in food industry to modify dairy products (see D3). The subject-matter of claims 8, 9, 11-13, 16, 17, 20, 21 hence is obvious in the light of D1, D2 and D3.

On the other hand, the claimed strain of *Bifidobacterium bifidum* according to claims 3-5 and its use according to claims 15 is neither disclosed nor suggested in the prior art.

Re Item VIII

Certain observations on the international application

Claims 1-4 define the essential features of the claimed strain of *Bifidobacterium bifidum* by functional definitions ("result to be achieved") and therefore lack clarity within the meaning of Article 6 PCT.

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(SEPARATE SHEET)**

International application No.

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Claim 4 is furthermore unclear in so far as the conditions of the enzymatic transformation of lactose to galacto-oligosaccharides are not mentioned. It is well-known that the pH-value, the lactose concentration and the reaction time have an influence on the proportions of the resulting disaccharides, trisaccharides etc. (compare D2, fig. 1 at page 346).

The expression "or a biological functional equivalent" renders the scope of claim 5 unclear.